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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 :
A61M 16/20, A62B 9/02, F16K 11/044, 27/02, B63C 11/14

A1

(11) International Publication Number: WO 98/26830

(43) International Publication Date: 25 June 1998 (25.06.98)

(21) International Application Number: PCT/AU97/00849

(22) International Filing Date: 16 December 1997 (16.12.97)

(30) Priority Data:
PO 4229 16 December 1996 (16.12.96) AU

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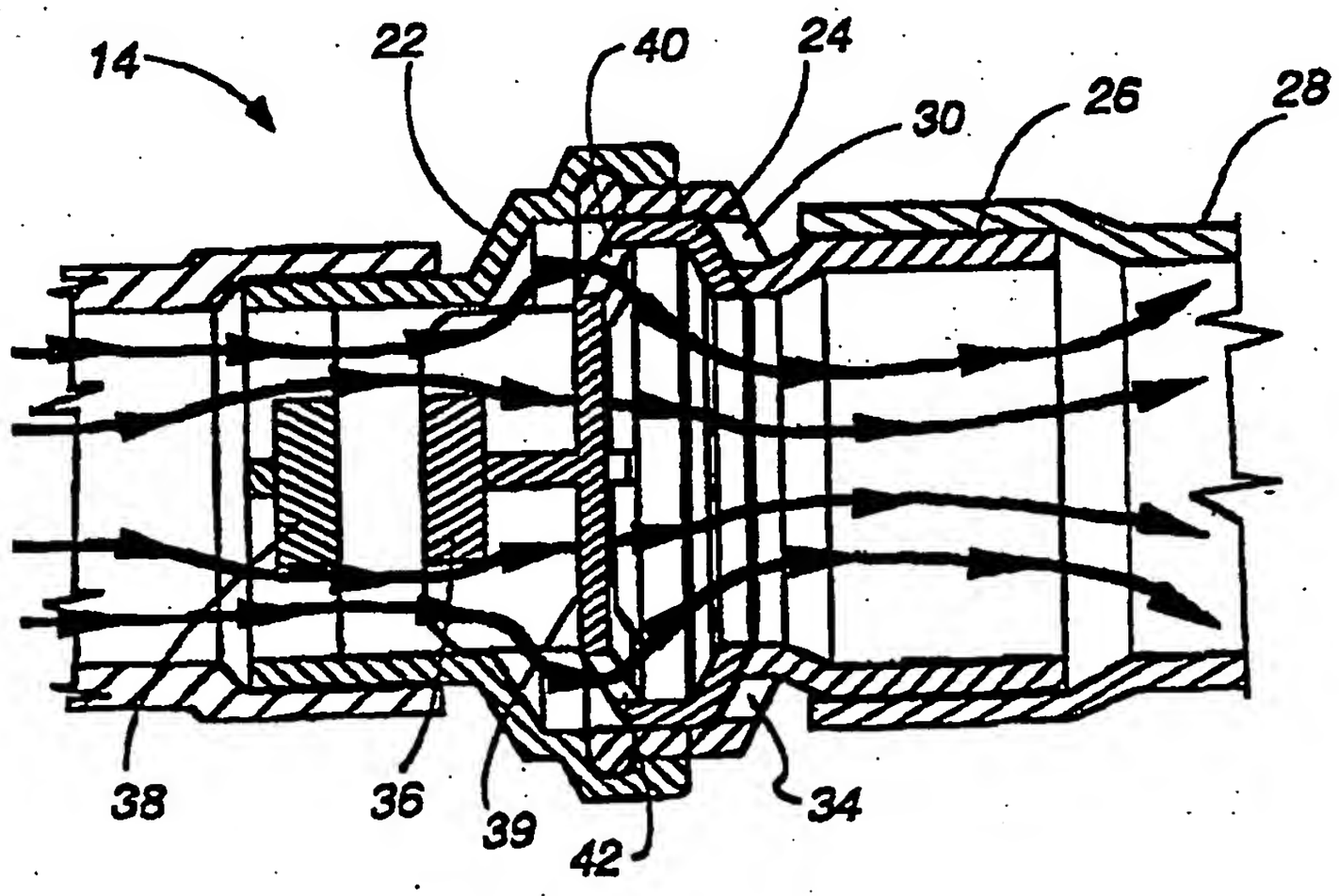
(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, GW, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

Published
With international search report.

(54) Title: NON RETURN SLIDER VALVE USED IN RESPIRATION SYSTEMS

(57) Abstract

The valve (14) comprises a housing (22) and a slider element (24) connected to a mask housing (26). During normal operation side ports (30, 34) are closed by element (24). The air flow to a patient must be sufficient to overcome the slight attractive force between magnets (36, 38). If the flow from the generator drops to below the level necessary to keep the slider element to the open position, the magnets move together allowing plate (39) to stop flow to the patient, who may breath unassisted through the side ports.



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NON RETURN SLIDER VALVE USED IN RESPIRATION SYSTEMS

Field of the Invention

The present invention relates to a valve and in particular to a valve adapted to, in use, be disposed between a patient and a means to deliver a breathing gas in a substantially closed system.

Background of the Invention

Nasal masks are currently employed for various purposes, including the delivery of oxygen to persons who suffer from lung disease or who are exposed to rarefied atmospheres, for administering anaesthetic gases and for delivering pressurized air to persons who suffer from disorders such as sleep apnea. The masks usually are moulded from a relatively soft, resilient, elastic material and they are shaped during manufacture to match the facial contours of an average intended wearer. However, a problem with the known types of masks is that, because individuals vary so much from the average, the masks must be forced against their inherent resiliency to deform and so adapt to the shapes of the users in order to avoid gas leakage. This requires that the masks be secured firmly by retaining straps or harnesses in order to prevent air leakage.

Flow generators are typically utilized to deliver a breathable gas to a patient wearing a mask. The flow generator is generally connected to flexible tubing which is secured to a mask worn by a patient. If the flow generator's operation is interrupted as a result of a power outage or other mechanical or electrical failure, there may be a significant build up of carbon dioxide in the mask as the patient's exhaled air is not washed out of outlet vents which are usually contained in the mask. This may present a health problem to the patient. Additionally, when oxygen is added to the breathable gas delivered by a flow generator in a closed circuit, and there is a failure of the flow generator, oxygen may still be delivered to the circuit. If and when power is restored to the flow generator, there may be a significant amount of oxygen present in the flow generator creating a possible explosion hazard. Finally, there are often humidifiers

used with flow generators. Any water from the humidifier should be prevented from entering the generator.

There have been numerous patents which have addressed some sort of safety valve for gas or air delivery masks. An example of such a patent is U.S. Patent No. 5,438,981. This patent discloses a counter balanced, rigid valve element which depending on the gas flow, either covers an opening to the ambient air or covers the gas flow airway such that the air or breathing gas is forced out into the ambient air opening. However, this system suffers from being a fairly complicated and expensive system which must rely on a counter balanced moving part. Additionally, if any condensation from the air gets on or around the balanced valve element, the operation of this valve element may be compromised. Finally, this valve is difficult to clean.

It is an object of the present invention to overcome or at least ameliorate one or more deficiencies of the prior art.

Summary of the Invention

Accordingly, in a first aspect, the present invention provides a valve adapted to, in use, be disposed between a patient and means to deliver a breathing gas in a substantially closed system, the valve comprising:

(a) an outer housing having at least one port for venting the breathing gas to atmosphere, thus making the system an open system;

(b) a slider element adapted to fit within the housing, said slider element moveable in the housing between at least a first position wherein the slider element substantially blocks the port(s) such that system is closed and a second position wherein the slider element does not substantially block the port(s) such that the system is open to atmosphere; and

(c) a force means applying a force to the slider element to bias the slider element from the first position to the second position.

Preferably, the force means comprises a first magnet on the slider element and a second magnet on the housing, the magnets being positioned such that the returning force does not exceed the force applied to said slider element when the pressure present

in said closed system is above a predetermined level. The predetermined level is preferably about one to three centimetres of water.

Desirably, the housing comprises two housing parts, a means to deliver gas housing and a mask housing, the mask housing includes the port(s).

In an embodiment, housing has a plurality of ports.

The second position preferably results from the means to deliver a breathing gas not generating the gas in sufficient volume to maintain the pressure in said closed system above a predetermined level. The predetermined level is desirably one centimetre of water.

The housing and the slider element preferably have engageable housing and slider shoulders, such that when the slider element is in the first position, the slider shoulder abuts the housing shoulder in an engaging fashion.

In another embodiment, the valve is integral with the mask.

In yet another embodiment, the valve is integral with the means to deliver a breathing gas.

In a second aspect, the present invention provides a valve having a first end and a second end, said first end secured to a flexible tubing which in turn is secured to a means to deliver a breathing gas, said second end secured to a breathing mask which is secured to a patient, said valve, means to deliver a breathing gas and tubing defining a system which in a first operational mode is a substantially closed system, said system defined by the means to deliver a breathing gas secured to a flexible tubing which is secured to said safety valve which is secured to said mask, said safety valve comprising:

(a) an outer housing, said outer housing having a gas delivery housing and a mask housing, said gas delivery housing having a first shoulder, said mask housing having a second shoulder, said second shoulder having at least one port therethrough for the purpose of venting the closed system to the atmosphere in a second operational mode;

(b) a slider element, said slider element being configured to fit within said housing, said slider element having a third shoulder comprising an aperture therethrough, and a fourth shoulder, said slider element having at least two positions engageable within said housing, a first position wherein said fourth shoulder of said slider element substantially engages said second shoulder of said mask housing such that said port(s) is/are substantially blocked, thereby resulting in said first operational mode, a second position wherein said third shoulder of said slider element substantially engages said first shoulder of said gas housing thereby resulting in said second operational mode; and

(c) a force means applying a returning force to said slider element, said force biasing said slider element from said first position to said second position.

The valve preferably has a plurality of ports and a plurality of apertures.

The force means preferably comprises a first magnet on the slider element and a second magnet on the gas delivery housing, the magnets being positioned such that the returning force does not exceed the force applied to the slider element when the atmospheric pressure present in the first operational mode is above a predetermined level. The predetermined level is desirably about one to three centimetres of water.

Brief Description of the Drawings

Preferred embodiments of the invention will now be described, by way of example only, with reference to the accompanying drawings in which:

Figure 1 is a general schematic drawing of a system comprising a flow generator being connected to a valve and mask via tubing in which the mask is connected to a patient;

Figure 2 is a side view of a valve of the present invention;

Figure 3 is a cross sectional view of the figure of figure 2;

Figure 3A is the cross sectional view of Figure 3 with airflow from the flow generator being show;

Figure 4 is a cross sectional view of the valve of the present invention wherein the flow of air from the generator has stopped;

Figure 4A is the view of Figure 4 wherein the direction of air is illustrated with the use of arrows;

Figure 5 is an exploded view of the valve shown in Figures 2-4;

Figure 6 is an end view of one of the valve elements shown in Figure 5;

Figure 7 is a side view of the valve element shown in Figure 6;

Figure 8 is an end view of one of the elements shown in Figure 5;

Figure 9 is a side view of the element shown in Figure 8;

Figure 10 is an end view of one of the elements shown in Figure 5;

Figure 11 is a side view of the element shown in Figure 10;

Figure 12 is an exploded perspective view of Figure 5;

Figure 13 is an exploded perspective from the other end of that shown in Figure 12;

Figure 14 is an exploded view of an alternative embodiment of the present invention wherein the valve is incorporated into the mask;

Figure 15 is a perspective view of an alternative embodiment of the present invention wherein the valve is incorporated into the mask;

Figure 16A is a cross sectional view of an alternative embodiment of the present invention showing the airflow from the generator to the mask; and

Figure 16B is the alternative embodiment shown in Figure 14A wherein the flow generator has ceased to operate and the gas flow is from the mask out to the ambient air.

Detailed Description of the Preferred Embodiments

The present invention can be used for any air or oxygen delivery system wherein there is some type of flow generator hooked up to a tube or airflow conduit which is thereafter secured to a mask which is secure to a patient. The gas being transmitted can be any type of breathing or therapeutic gas. The general schematic of this is shown in Figure 1 wherein there is a flow generator 10 having an air flow tube 12 secured to a schematic of the valve of the present invention 14 which is thereafter connected to a mask 16 of a patient 20. The mask shown is just an example of

numerous types of breathing-patient interfaces. Although the present invention's valve can be used for any type of closed air delivery system, it is preferably used in CPAP applications. CPAP (continuous positive airway pressure) is a therapy developed by Dr. Colin Sullivan, as described in U.S. Pat. No. 4,944,310 which treats, among other things, the sleep disorder of sleep apnea. CPAP therapy requires pressurized air delivered out of a flow generator, such as that shown as 10 in Figure 1, to a patient 20. Pressurized air acts to force open the air passages of a patient, thus preventing the temporary occlusion of airway passages which are typical in sleep apnea patients.

The location of the valve 14 shown in Figure 1 is just one example of a location under this invention. Valve 14 could be connected to mask 16, or it could be an integral part of mask 16, as shown in figures 14 and 15. It also could be located at the outlet of the flow generator 10. There could also be two or more valves located on a single system. It is preferred to put the valve 14 as close to the mask 16 as possible, or to make it part of the mask 16.

The flow generator 10 can be a CPAP flow generator, bottled gas, a respirator, or any other type of device that delivers breathable, therapeutic or anaesthetic gas.

Figure 2 is a close up of the valve 14 shown in Figure 1, which is more easily seen in Figure 5. The valve in Figure 2 has three parts. It has what will be referred to as a flow generator housing or means to deliver gas housing 22, slider element 24 (visible in Figures 3, 3A, 4, 4A, 8, 9, 12, and 13) and mask housing 26. The normal air flow for the valve 14 shown in Figures 2 and 3A comes from the flow generator from the direction of the flow generator housing 22 wherein it passes through the flow generator housing 22, through valve element 24 through mask housing 26 and into tube 28. During the normal operation wherein the flow generator is generating a flow of gas, the ports identified as 30, 32 and 34 are closed to atmosphere or the open air, and the air flows through the valve 14 into tubing 28 wherein the air flows into the mask shown as 16 in Figure 1. This airflow is best shown in Figure 3A wherein the arrows

indicate the airflow. The airflow comes through tube 12, into flow generator housing 22, whereby it enters the slider element portion of the valve 24.

The slider element 24 has at least two positions. The two positions are shown in Figures 3A and 4A. In Figure 3A, slider valve element 24 is forced open by the airflow. The airflow overcomes the force generated by, in the preferred embodiment, magnets located at 36 and 38. The magnetic force imparted to the slider element 24 by magnets 36 and 38 is a very slight force, which is overcome by the flow of air shown in Figure 3A. Generally, this will be referred to as the returning force which acts to close the slider valve 24 in the event of decreased air flow. This returning force means can be any type of force which imparts a force on the slider valve 24 to close in the event that airflow is terminated or diminished. A preferred force is a magnetic force, but in other embodiments (not shown) springs, electro magnetic pulses, elastic materials, gravity, or other biasing forces are non-limiting examples of other types of forces are used. These are merely examples of biasing forces, other structural mechanisms are also used to close the slider valve 24 in the event that airflow is terminated or slowed to the extent that not enough air is delivered to the patient. It is important to note that the airflow from the flow generator 10 does not have to be terminated, but rather if there is decreased airflow, which might be insufficient to satisfy the pulmonary needs of the patient, then the valve can be configured to close under those conditions.

During normal operation, the airflow from the generator 10 flows around what is identified as base plate 39 of the slider valve 24. This base plate 39 is a structure on which a component of the returning force may be secured onto the slide valve 24. The returning force may be located or secured at positions other than the base plate 39. The air flows around said base plate 39, and it also flows through port holes 40 and 42. It is important to note that a single port hole or a multitude of port holes can be used. Thereafter, the air flows into mask housing 26 then tube 28 which leads to the mask of the patient or in another embodiment, directly from mask housing 26 into mask 16. The terms "flow generator housing" and "mask housing" are not meant to assert that

these housings are part of the flow generator or mask. Rather, this is merely to indicate the position of the valve housing, e.g., the flow generator housing means that part of the valve housing which is closest to the flow generator 10 and the mask housing is that portion of the valve housing which is closest to the mask 16. However, the housings can be a part of the mask 16 or flow generator 10 in embodiments that fall within the scope of this invention. This would include the valve being an integral part of the mask 16 or flow generator 10, which means there is no tubing connecting the valve to either the mask or flow generator.

Figure 4A illustrates the slider valve element 24 wherein the airflow from the flow generator has diminished to the point where it does not override the attractive or biasing force pulling the slider valve element 24 closed. What occurs in Figures 4 and 4A is the force of the air which had originally been pushing on base plate 39 keeping the valve 14 open has decreased to a point such that the attraction of the two magnets 36 and 38 is not overcome anymore. The slider valve 24 then moves to the left, thereby closing off the ability of the air to flow freely between the flow generator and the mask. In the preferred embodiment, both 36 and 38 are magnets. However, as described above, there are many options, and the other options would be that one of the elements, e.g., 36 would be a magnet wherein element 38 would merely be some material capable of being attracted to a magnet, such as iron, or an iron composite. As shown in Figure 4a, the airflow would thus occur through ports 30 and 34. In this mode, the patient 20 is breathing on his or her own, and the air is flowing in both directions, and is open to the atmosphere through ports 30 and 34. As is shown in later figures, there are many ports, thus the flow of oxygen or any gas moves quite freely through the ports 30, 32 and 34, into the mask housing 26 and into the patient's respiratory system.

Figure 5 is an exploded view of the valve shown in Figures 1-4. Although Figure 5 shows essentially three separate components, in other embodiments only 2 components are necessary, wherein the slider valve 24 fits within flow generator housing 22, which would be moulded to achieve the general structure of mask housing

26. In other words, there would be a one piece outer housing, which would essentially be a combination of housings 22 and 26 wherein slider element 24 would be contained therein.

Figures 6-11 are side and end views of the various elements of the present invention.

Figures 12 and 13 are exploded perspective views illustrating the preferred embodiment of the valve of the present invention. As can be seen, the elements are easily moulded components preferably out of an engineered polymer or thermoplastic. It is important to note that the valve can be easily taken apart and thereafter easily reassembled.

Figures 14 and 15 illustrate embodiments which incorporate the valve 14 into the mask 16. These embodiments have the advantage of not needing to make the additional connections of the airflow tube between the mask and the valve.

Figures 16A and 16B illustrate an alternative embodiment of the present invention wherein there are just two elements, that being the outer housing 60 and the slider element 62. Figure 16A illustrates the natural flow wherein the air flows from a generator side 64 to a mask side 66. This flow overcomes some slider element force, which could include the use of the magnetic force disclosed earlier and is shown as magnets 68 and 70 in phantom. Air flows through port 72 and 74. Once the airflow is lessened or terminated, the returning force is not overcome, wherein Figure 16B illustrates the alternative embodiment of the safety valve of the present invention with the airflow open to the atmosphere, flowing through ports 76 and 78.

The present invention has the advantages of being able to fit all nasal and mouth mask systems. This includes both adults and infants. In the situation of infants, the airflow may be less, and thus the force needs to open the slider valve may be adjusted accordingly. Typically, the slider valve is set such that if pressure falls below about one to three centimetres of water, the valve will vent to the atmosphere. If the airflow pressure is greater than one to three centimetres of water, the slider valve will remain closed to the atmosphere. Preferred embodiments of the valve of the present

invention have the advantage of being able to operate independent of orientation. That is, although it has to be connected in the right direction between the flow generator and the mask, it can be inverted, held sideways, etc. which often occurs during the time when the patient sleeps. This is an important advantage over the prior valves. Additionally, there are some flow generators which start and stop purposely, such as ResMed's SmartStart and Autoset flow generators and the present invention can accommodate such starting and stopping wherein the slider valve element will open and close accordingly.

The valve of the present invention also has few moving parts providing easier and more consistent operation in the event of moisture or condensation entering the valve.

The valve of the present invention is also very easily cleaned, and may be disassembled, cleaned and reassembled very easily at home or at a hospital or clinic. A humidifier may also be used, and will be attached as a separate device at the flow generator or other location.

Although the invention has been described with reference to specific examples, it will be appreciated by those skilled in the art that the invention may be embodied in many other forms.

CLAIMS:

1. A valve adapted to, in use, be disposed between a patient and means to deliver a breathing gas in a substantially closed system, said valve comprising:

(a) an outer housing, said outer housing having at least one port for the purpose of venting the breathing gas to the atmosphere; thus making the system an open system;

(b) a slider element, said slider element being configured to fit within said outer housing, said slider element having at least two positions engageable within said housing, a first position wherein said slider element substantially blocks said port(s) such that said system is closed, a second position wherein said slider element does not substantially block said port(s) such that said system is open to said atmosphere; and

(c) a force means applying a returning force to said slider element, said force biasing said slider element from said first position to said second position.

2. The valve of claim 1 wherein said returning force comprises a first magnet on said slider element and a second magnet on said outer housing, said magnets positioned such that the returning force does not exceed the force applied to said slider element when the atmospheric pressure present in said closed system is above a predetermined level.

3. The valve of claim 1 or 2 wherein said predetermined level is about one to three centimeters of water.

4. The valve of any one of claims 1 to 3 wherein said outer housing has a plurality of ports.

5. The valve of any one of claims 1 to 4 wherein said outer housing comprises two housing parts, a means to deliver gas housing part and a mask housing part, said mask housing part including said port(s).

6. The valve of any one of claims 1 to 5 wherein said second position results from said means to deliver a breathing gas not generating said gas in sufficient volume to maintain at least one centimeter of pressure in said closed system.

7. The valve of any one of claims 1 to 6 wherein said housing and said slider element has engageable housing and slider shoulders, such that when said slider element is in said first position, said slider shoulder abuts and engages said housing shoulder.

8. The valve of any one of claims 1 to 7 wherein said valve is integral with said mask.

9. The valve of any one of claims 1 to 8 wherein said valve is integral with said means to deliver a breathing gas.

10. A valve having a first end and a second end, said first end secured to a flexible tubing which in turn is secured to a means to deliver a breathing gas, said second end secured to a breathing mask which is secured to a patient, said valve, means to deliver a breathing gas and tubing defining a system which in a first operational mode is a substantially closed system, said system defined by the means to deliver a breathing gas secured to a flexible tubing which is secured to said safety valve which is secured to said mask, said safety valve comprising:

(a) an outer housing, said outer housing having a gas delivery housing and a mask housing, said gas delivery housing having a first shoulder, said mask housing having a second shoulder, said second shoulder having at least one port therethrough for the purpose of venting the closed system to the atmosphere in said second operational mode;

(b) a slider element, said slider element being configured to fit within said housing, said slider element having a third shoulder comprising at least one aperture therethrough, and a fourth shoulder, said slider element having at least two positions engageable within said housing, a first position wherein said fourth shoulder of said slider element substantially engages said second shoulder of said mask housing such that said port(s) is/are substantially blocked, thereby resulting in said first operational mode, a second position wherein said third shoulder of said slider element substantially engages said first shoulder of said gas housing thereby resulting in said second operational mode; and

(c) a force means applying a returning force to said slider element, said force biasing said slider element from said first position to said second position.

11. The valve of claim 10 wherein there are a plurality of said ports and a plurality of said apertures.

12. The valve of claim 10 or 11 wherein said returning force comprises a first magnet on said slider element and a second magnet on said gas delivery housing, said magnets positioned such that the returning force does not exceed the force applied to said slider element when the atmospheric pressure present in said first operational mode is above a predetermined level.

13. The valve of any one of claims 10 to 12 wherein said predetermined level is about one to three centimeters of water.

14. The valve of any one of claims 10 to 13 wherein said second position results from said means to deliver a breathing gas not generating said gas in sufficient volume to maintain at least one centimeter of pressure in said closed system.

15. The valve of any one of claims 10 to 14 wherein said valve is integral with said mask.

16. The valve of any one of claims 10 to 15 wherein said valve is integral with said means to deliver a breathing gas.

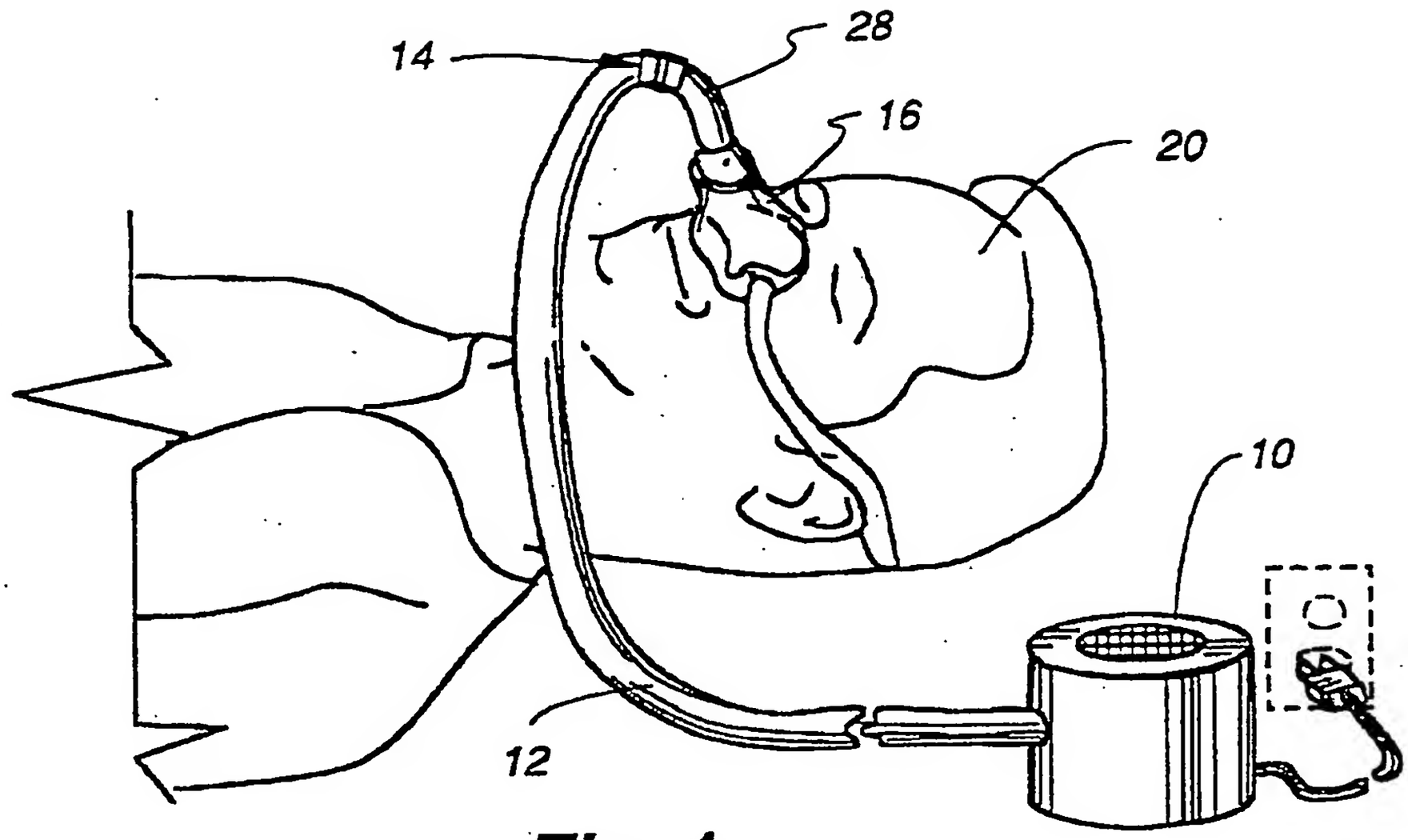

Fig. 1

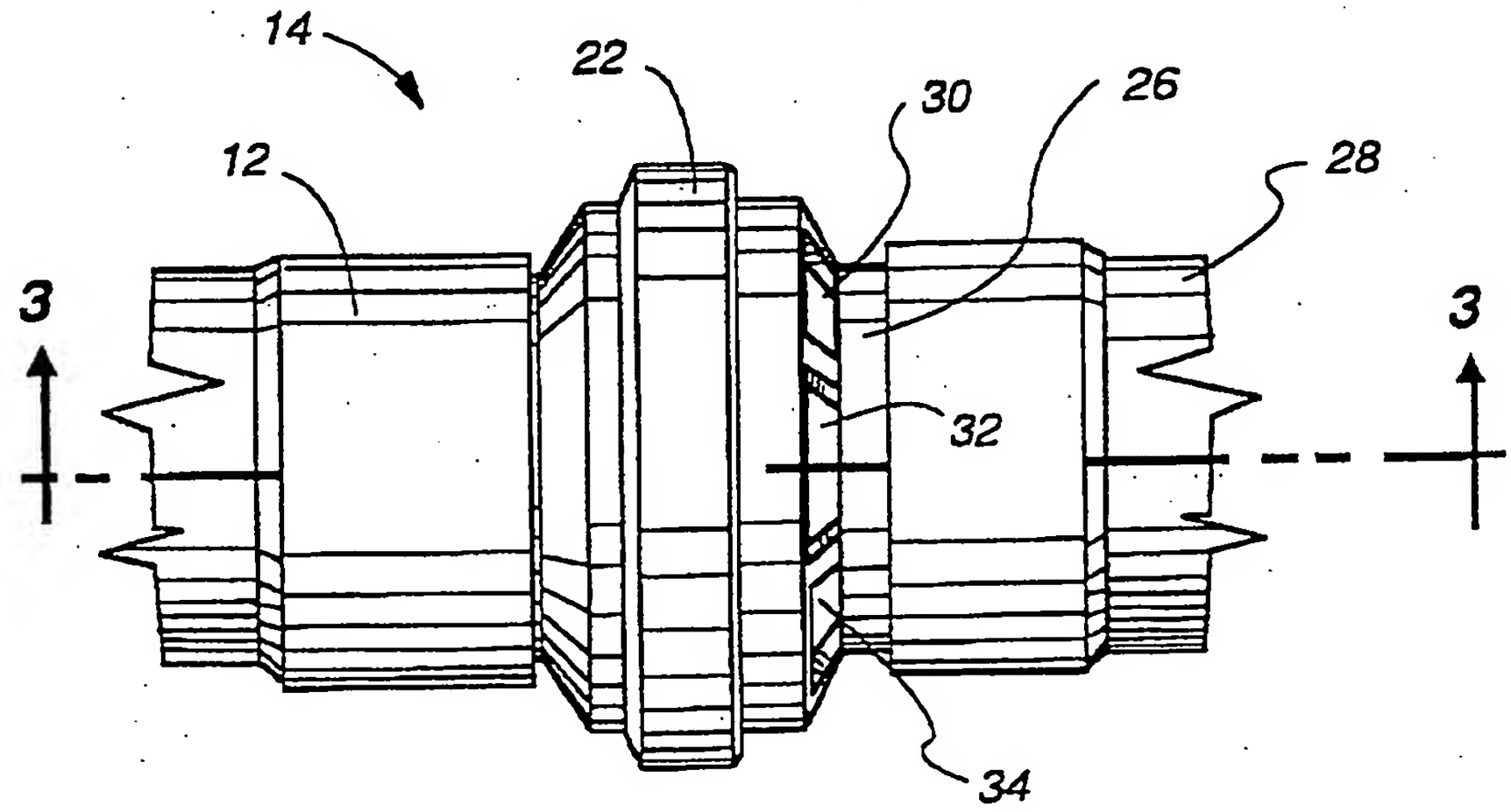

Fig. 2

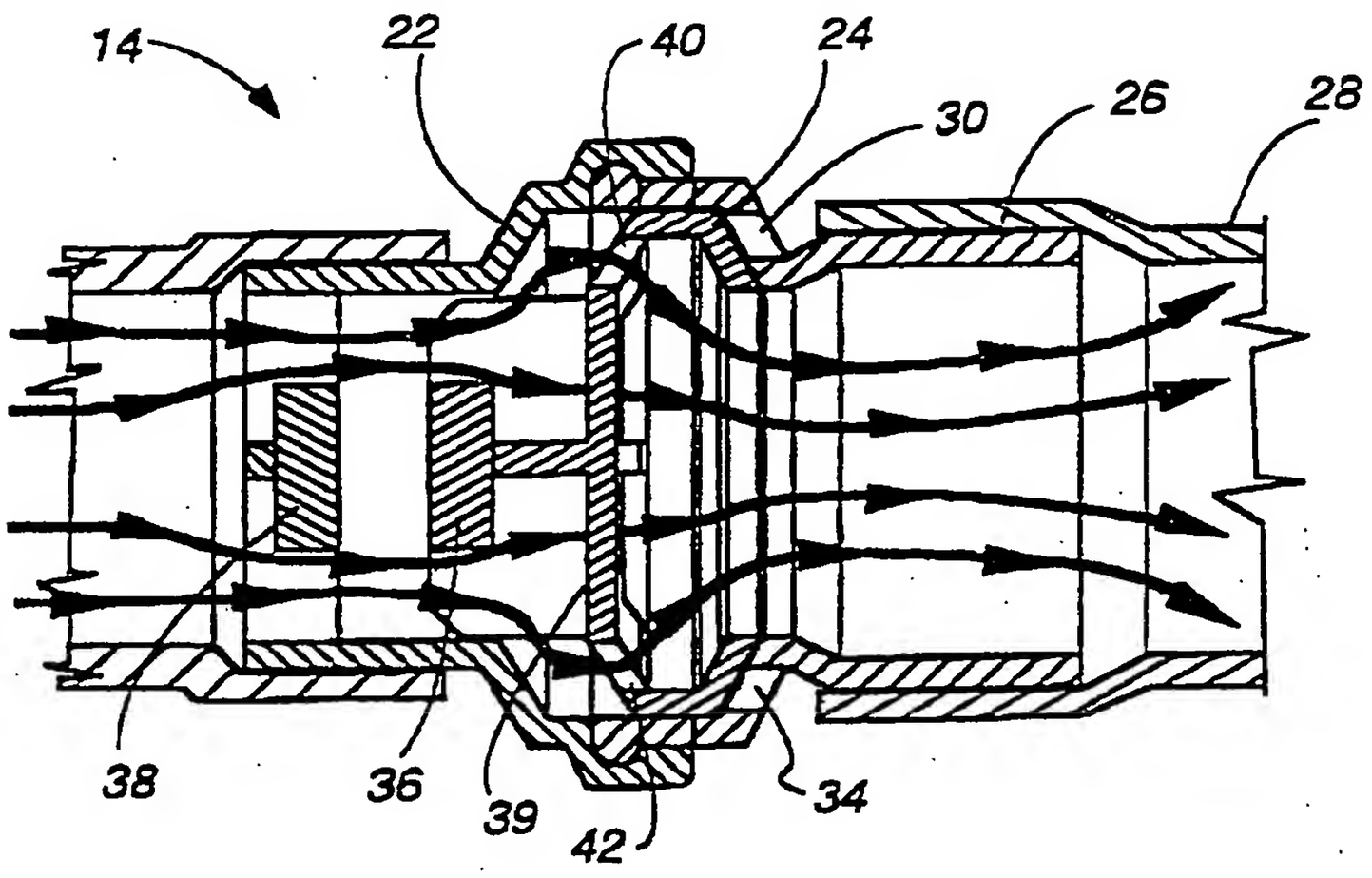

Fig. 3A

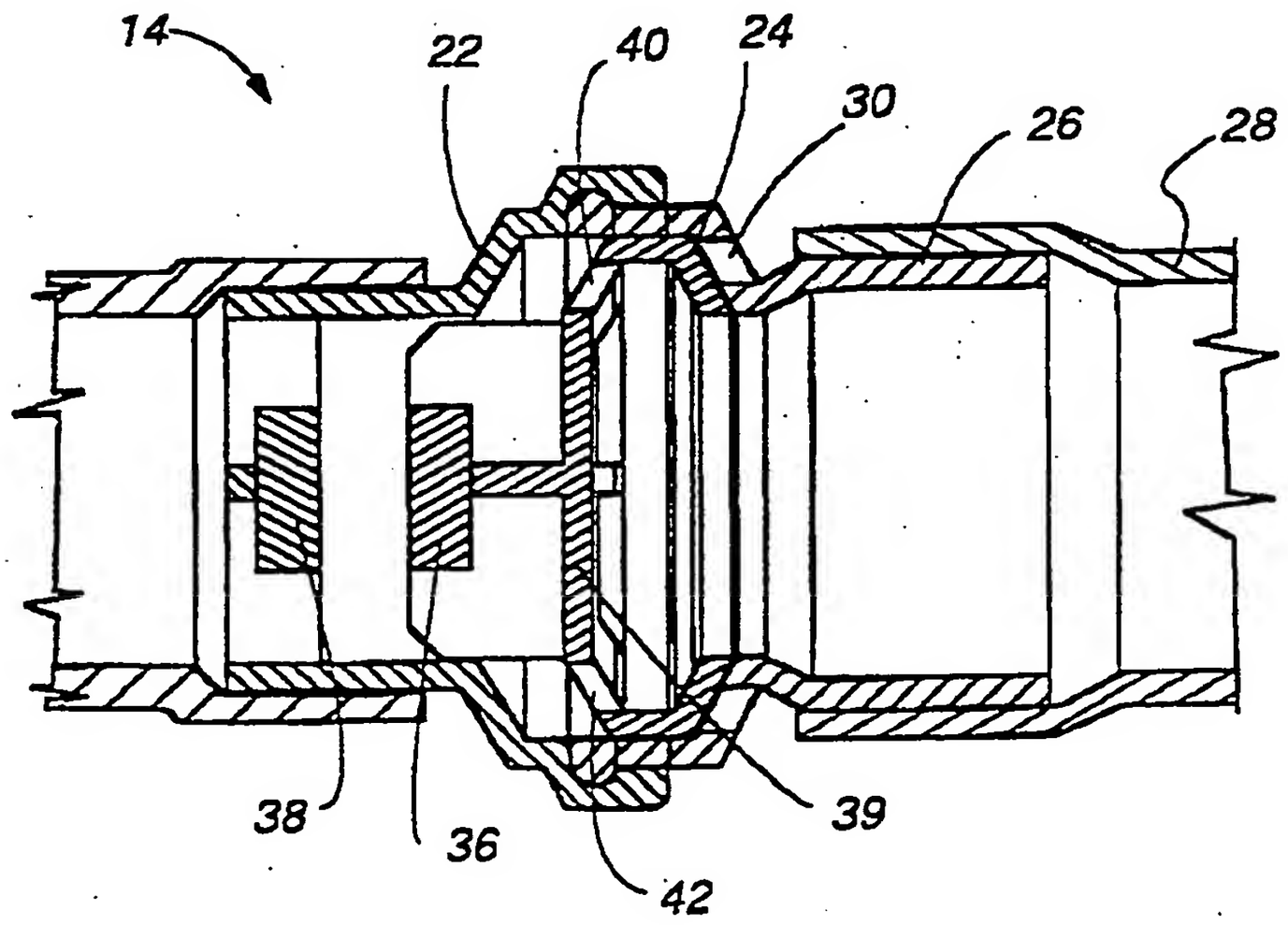

Fig. 3

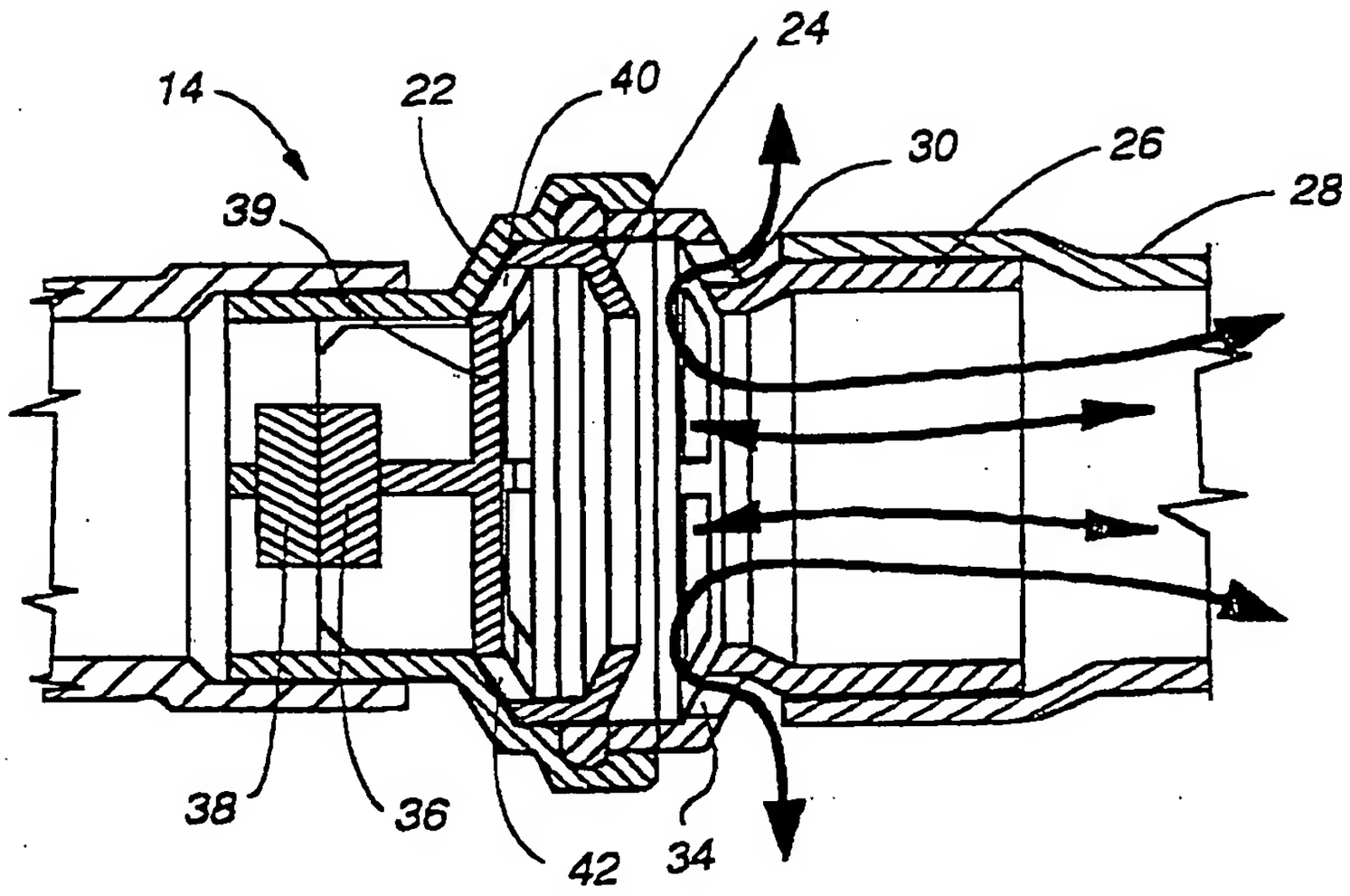

Fig. 4A

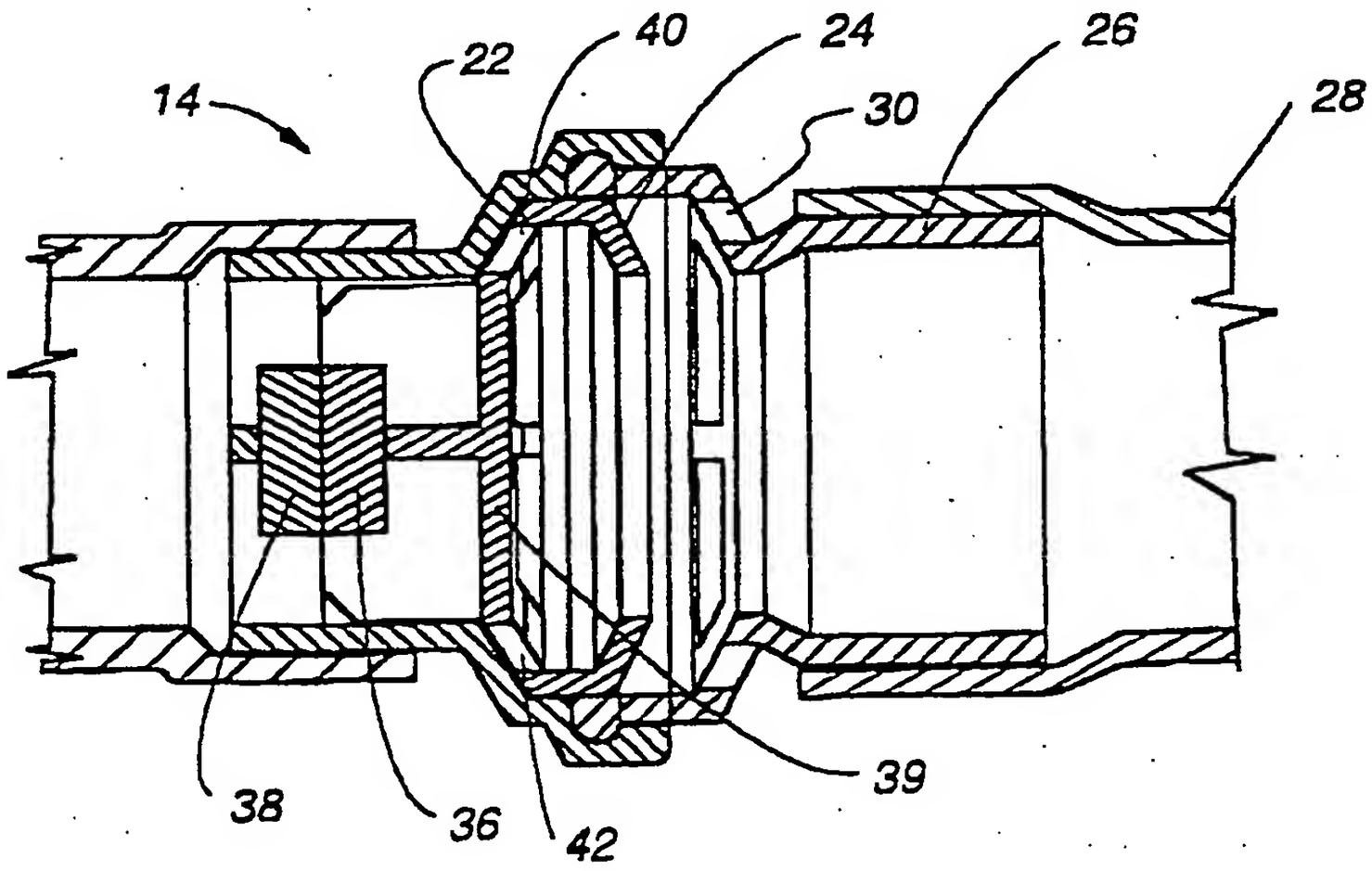

Fig. 4

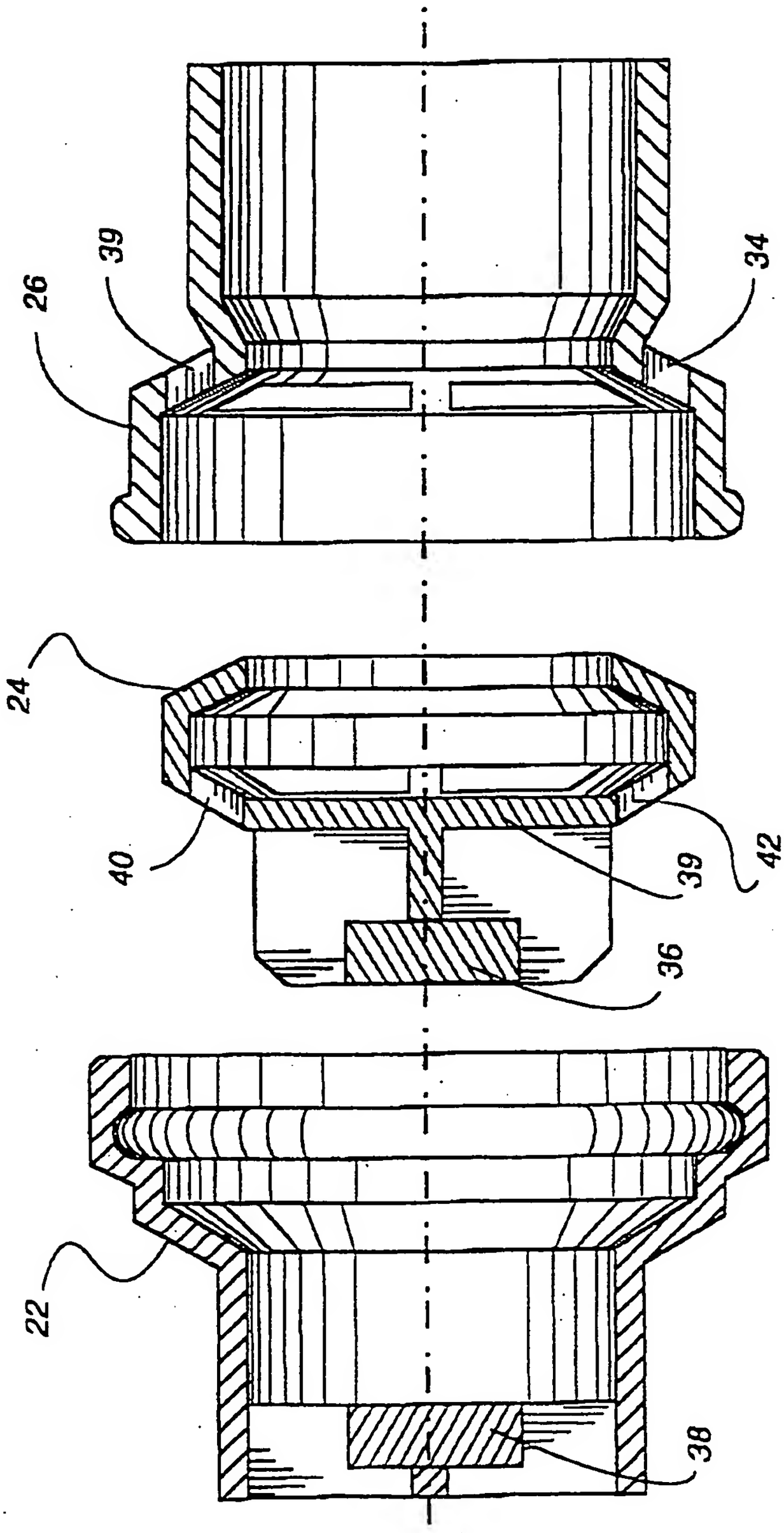

Fig. 5

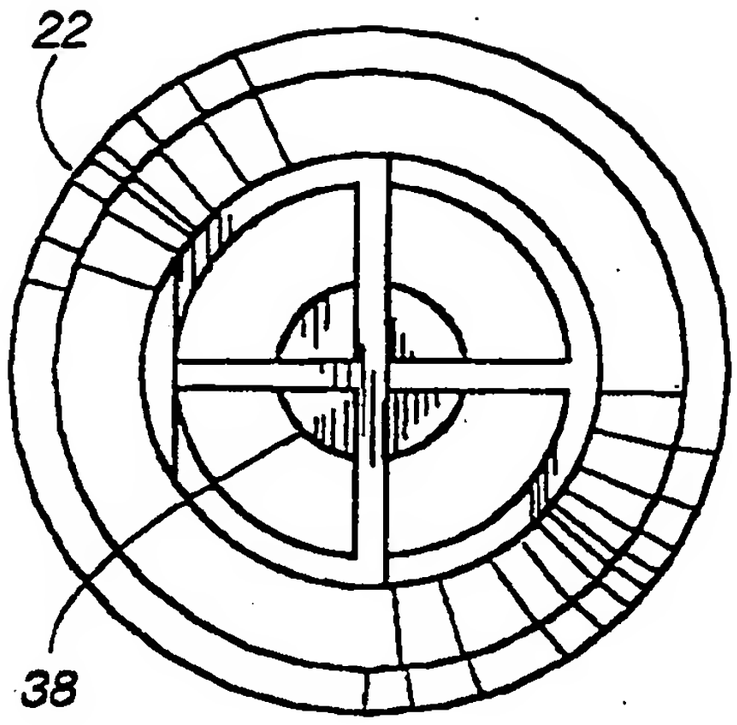

Fig. 6

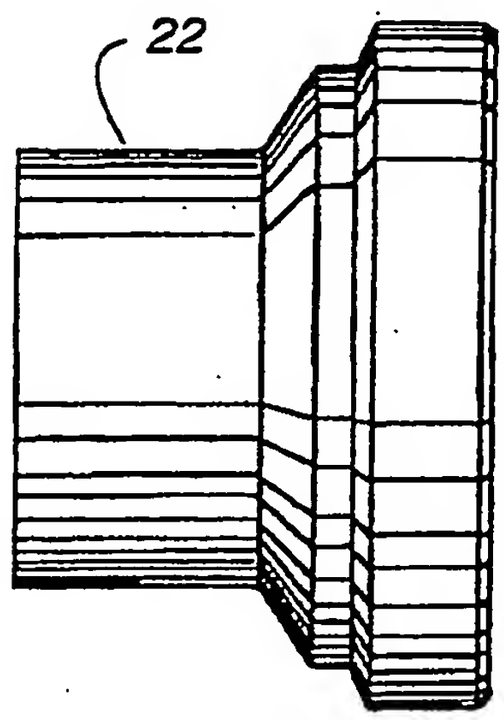

Fig. 7

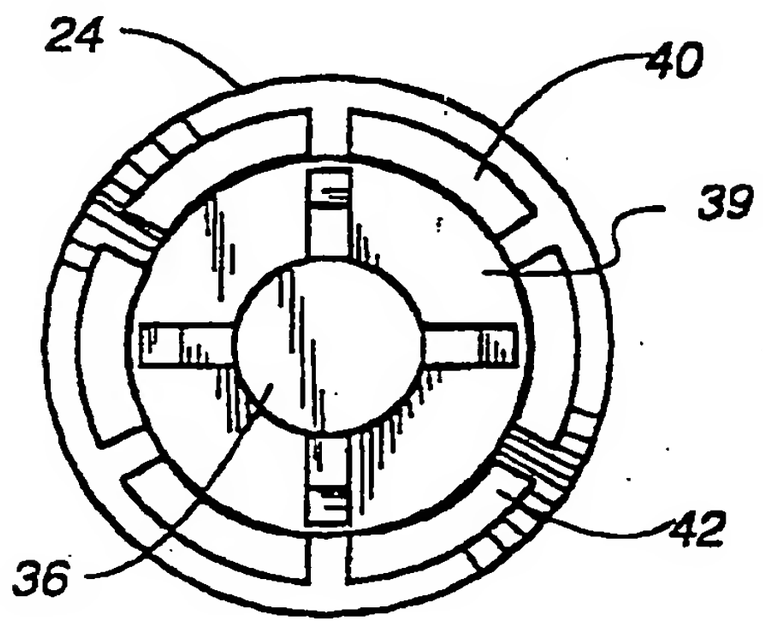

Fig. 8

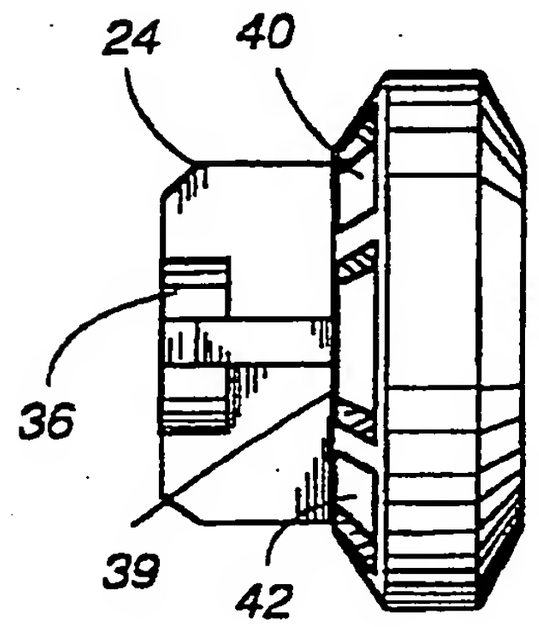

Fig. 9

Fig.10

Fig.11

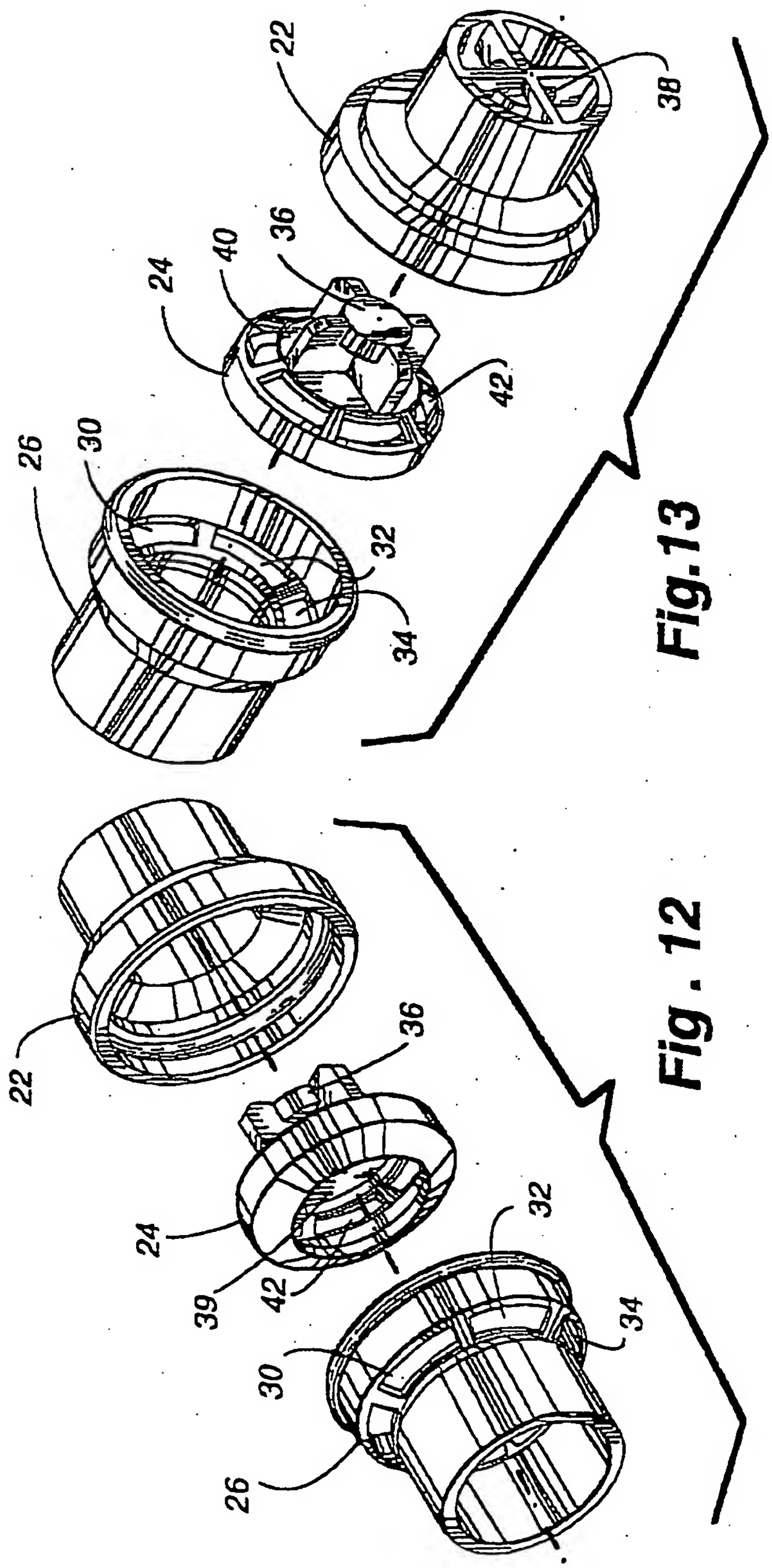

Fig. 12

Fig.13

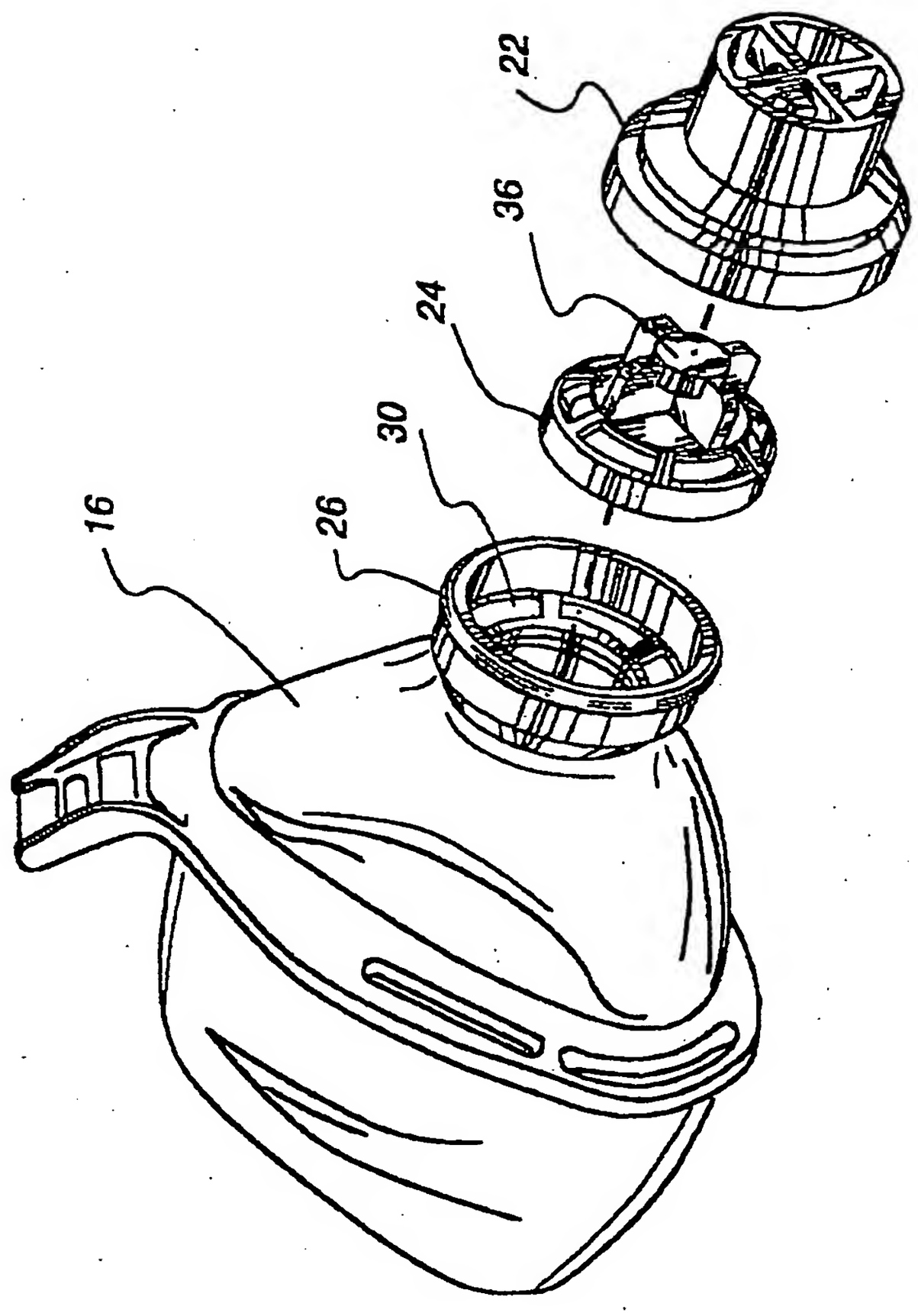

Fig. 14

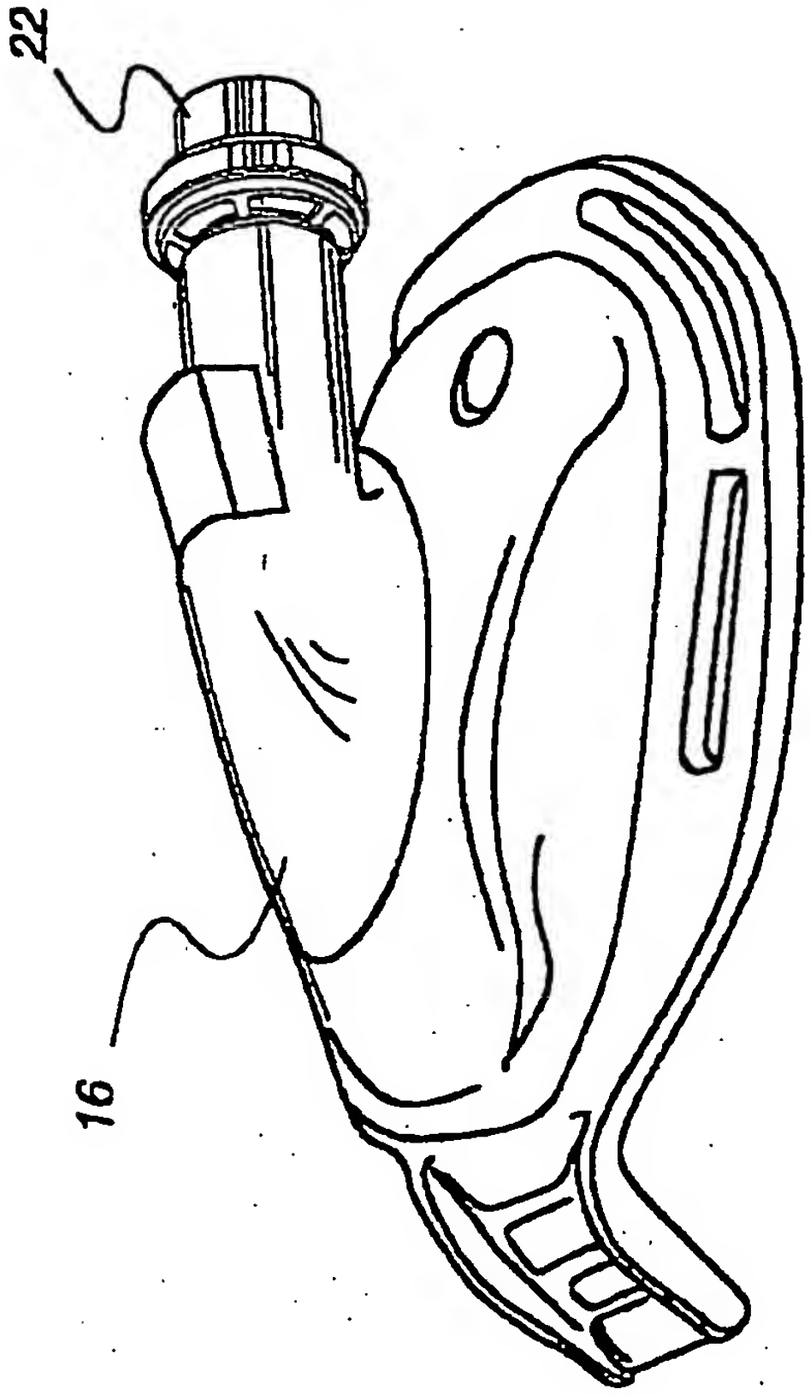

Fig. 15

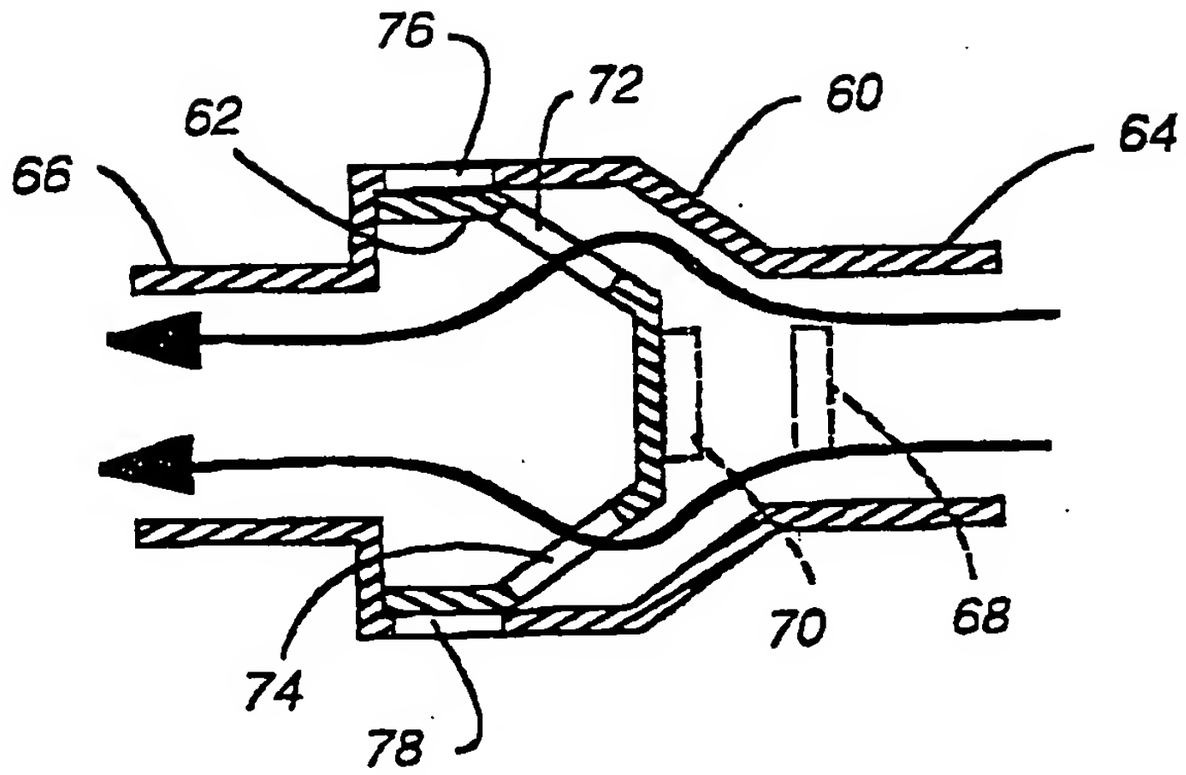

Fig. 16 A

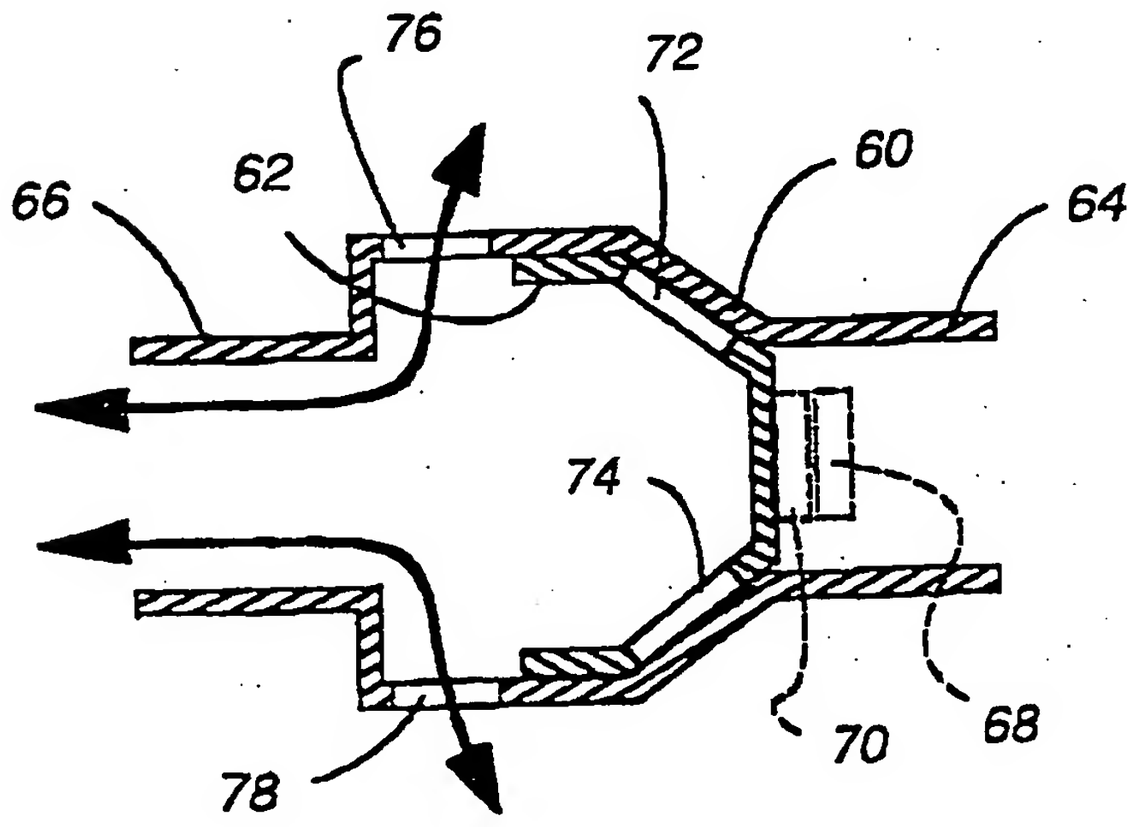

Fig. 16 B

INTERNATIONAL SEARCH REPORT

Internauonal Application No.
PCT/AU 97/00849

A. CLASSIFICATION OF SUBJECT MATTER

Int Cl[6]: A61M 16/20 A62B 9/02 F16K 11/044. 27/02 B63C 11/14

According to Internauonal Patent Classificauon (IPC) or to both nauonal classificauon and IPC

B. FIELDS SEARCHED

Minimum documentauon searched (classificauon system followed by classificauon symbols)
A61M A62B F16K B63C

Documentauon searched other than mınımum documentauon to the extent that such documents are included in the fields searched
AU IPC A61M 16/20 A62B 9/02

Electronic data base consulted during the internauonal search (name of data base and. where practicable. search terms used)
WPAT vent: port: exhaust: bias: spring magnet
JAPIO

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citauon of document. with indicauon. where appropriate. of the relevant passages	Relevant to claim No.
X	US 4870963 A (CARTER) 3 October 1989 column 4 line 63 to column 5 line 55. column 5 line 64 to column 6 line 24. figures 3 to 5	1, 4-9
X	US 5370356 A (PESOVIC et al) 6 December 1994 column 2 lines 54 to 62. column 3 lines 27 to 58. figure 1	1-9
X	US 5398673 A (LAMBERT) 21 March 1995 column 4 line 3 to column 6 line 15. figures 3 to 7	1. 4-11. 13-16

[X] Further documents are listed in the continuation of Box C

[X] See patent family annex

* Special categories of cited documents:

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"O" document referring to an oral disclosure. use. exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the internauonal filing date or priority date and not in conflict with the applicauon but cited to understand the principle or theory underlying the inventuon

"X" document of particular relevance: the claimed inventuon cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents. such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
23 January 1998	12 FEB 1998

Name and mailing address of the ISA/AU	Authorized officer
AUSTRALIAN INDUSTRIAL PROPERTY ORGANISATION PO BOX 200 WODEN ACT 2606 AUSTRALIA Facsimile No.: (02) 6285 3929	MATTHEW FORWARD Telephone No.: (02) 6283 2606

INTERNATIONAL SEARCH REPORT

International Application No.
PCT/AU 97/00849

C (Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4229832 A (DICKSON) 28 October 1980	
A	GB 2233237 A (ARAN FIRE & SAFETY (UK) LIMITED) 9 January 1991	
A	DE 3616267 A1 (JUERGEN BAELZ CONTROLS GESELLSCHAFT FUR MEB UND REQULTECHNIK MbH) 19 November 1987	
A	DE 4343205 A1 (FESTO KG) 22 June 1995	
A	JP 2-88078 A (TEJIN LTD) 28 March 1990	

INTERNATIONAL SEARCH REPORT

Information on patent family members

Internauonal Application No.
PCT/AU 97/00849

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member					
US	5370356	AU	12446/92	EP	493771	WO	92/11480

END OF ANNEX